UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

ROSALIE RICE,	)	
	)	
Plaintiff,	)	
	)	
	)	
vs.	)	**Case No.: 2:16-cv-01374-MHH**
	)	
ALLERGAN USA, INC.,	)	
	)	
Defendant.	)	

SUBSTITUTED MEMORANDUM OPINION[1]

This matter is before the Court on defendant Allergan USA's motion to dismiss. (Doc. 23). Allergan argues that federal law preempts plaintiff Rosalie Rice's state law claims and that Ms. Rice has not stated a plausible claim for relief pursuant to Federal Rule of Civil Procedure 12(b)(6). (Doc. 24). Ms. Rice concedes that she has not adequately pleaded some of her claims, and she has indicated that she is willing to dismiss those claims without prejudice. This opinion addresses Allergan's preemption defense with respect to the balance of Ms. Rice's claims.

STANDARD OF REVIEW

Rule 12(b)(6) enables a defendant to move to dismiss a complaint for

[1] The Court issues this substituted memorandum opinion to correct typographical errors on page 16. Otherwise, the memorandum opinion is identical to Doc. 28.

"failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Pursuant to Rule 8(a)(2), a complaint must contain, "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "Generally, to survive a [Rule 12(b)(6)] motion to dismiss and meet the requirement of Fed. R. Civ. P. 8(a)(2), a complaint need not contain 'detailed factual allegations,' but rather 'only enough facts to state a claim to relief that is plausible on its face.'" *Maledy v. City of Enterprise*, 2012 WL 1028176, at *1 (M.D. Ala. Mar. 26, 2012) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007)). "Specific facts are not necessary; the statement need only 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (quoting *Twombly*, 550 U.S. at 555).

A plaintiff does not have to "negate an affirmative defense in [her] complaint." *La Grasta v. First Union Securities, Inc.*, 358 F.3d 840, 845 (11th Cir. 2004) (internal quotation marks and citation omitted). A court may dismiss a claim on the basis of an affirmative defense when the plaintiff's "allegations, on their face, show that an affirmative defense bars recovery on the claim." *Cottone v. Jones*, 326 F.3d 1352, 1357 (11th Cir. 2003). The Court must "accept[] the allegations in the complaint as true and construe[] them in the light most favorable to the plaintiff." *Miljkovic v. Shafritz & Dinkin, P.A.*, 791 F.3d 1291, 1297 (11th Cir. 2015) (quoting *Hill v. White*, 321 F.3d 1334, 1335 (11th Cir. 2003)) (per

curiam) (internal marks omitted). The Court presents Ms. Rice's allegations accordingly.

BACKGROUND

Allergan manufactures and distributes the LAP-BAND, a surgically implanted medical device designed to help patients lose weight. (Doc. 18, ¶¶ 19–25, 45). The LAP-BAND is placed around the outside of the stomach to "create a small 'pouch' in the upper part of the stomach to control the speed by which food passes to the lower part of the stomach . . ." (Doc. 18, ¶ 19). Allergan's initial efforts to obtain FDA approval for the product were not successful. (Doc. 18, ¶ 21). The FDA gave premarket approval or PMA for the LAP-BAND in 2001. (Doc. 18, ¶ 22). Premarket approval reflects a great deal of investigation by the FDA and indicates that the FDA has found that there is "reasonable assurance" that the medical device is safe and effective when used under the conditions included in the device's label. The PMA also indicates that the FDA has concluded that the manufacturer's proposed labelling for the device "is neither false nor misleading." (Doc. 18, ¶ 9).

When the FDA granted PMA for the LAP-BAND, Allergan's label for the product indicated a 1% risk of erosion. (Doc. 18, ¶ 31). Erosion appears to occur

when the LAP-BAND slips and erodes into the stomach. (Doc. 18, ¶¶ 32, 36).[2] Erosion can require reoperation and removal of the LAP-BAND. (Doc. 18, ¶ 32).

After manufacturers like Allergan receive premarket approval, they must meet various reporting requirements. For example, they must report to the FDA adverse events associated with their product. (Doc. 18, ¶ 14). As a condition of PMA, Allergan agreed to conduct a post-approval clinical study to collect data on the long-term safety and effectiveness of the LAP-BAND. The clinical study had to include patient follow-up for five years post-implantation. (Doc. 18, ¶ 24). PMA also was conditioned on Allergan's compliance with general and device-specific requirements. (Doc. 18, ¶ 25). "Failure to comply with the conditions of approval invalidates [the PMA]. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act." (Doc. 18, ¶ 25).

Based on the results of its own studies, Allergan has maintained its disclosure of a 1% erosion rate for the LAP-BAND; however, outside medical studies "indicate a much higher complication rate." (Doc. 18, ¶¶ 26–31). Outside studies reveal that the possibility of erosion increases over time. (Doc. 18, ¶¶ 33–36) (listing a 2006 study indicating failure rates of 13.2% after 18 months, 23.8% after 3 years, 31.5% after 5 years, and 36.9% after 7 years, and finding a 9.5%

[2] In her complaint, Ms. Rice does not fully describe how erosion occurs. Viewing the allegations in the light most favorable to Ms. Rice, this is the Court's best understanding of LAP-BAND "erosion."

erosion rate after 5 years; a 2008 study indicating failure rates of 15% after 1 to 3 years increasing to 40% after 8 to 9 years; a 2011 study indicating a 28% erosion rate after 12 years; and a 2012 study indicating a 19.2% removal rate after 6 years with band erosion as the second most common cause of removal). Although the FDA generally must approve changes to product labels, a manufacturer may add to its label, without prior FDA approval, information that strengthens a warning or precaution about an adverse reaction when the additional information "enhance[s] the safe use of the product" or "delete[s] misleading, false, or unsupported indications." (Doc. 18, ¶ 13). Ms. Rice alleges that despite the erosion rate data from outside studies, Allergan "continues to represent in labelling and to the public erosion rates of approximately 1%." (Doc. 18, ¶ 31).

In early 2007, Ms. Rice's surgeon implanted the LAP-BAND to treat Ms. Rice for morbid obesity. (Doc. 18, ¶ 38). Toward the end of 2014, Ms. Rice began having difficulty swallowing, and she was vomiting frequently. (Doc. 18, ¶ 39). On November 26, 2014, Ms. Rice's surgeon discovered that the LAP-BAND "had eroded into [Ms. Rice's] stomach such that only the buckle itself was external to the stomach." (Doc. 18, ¶ 40) (internal marks omitted). Ms. Rice's surgeon removed the LAP-BAND and "repaired the gastric perforation caused by the eroded LAP-BAND." (Doc. 18, ¶ 40).

Ms. Rice filed this lawsuit on August 22, 2016. (Doc. 1). She alleged seven

state law causes of action against Allergan: negligence, strict liability failure to warn, design defect, manufacturing defect, breach of warranty, fraudulent misrepresentation, and violation of the Alabama Deceptive Trade Practices Act (ADTPA). (Doc. 18, ¶¶ 44–105). Pursuant to Rule 12(b)(6), Allergan has asked the Court to dismiss these claims based on express preemption, implied preemption, and failure to state a claim with sufficient factual specificity. (Doc. 24, pp. 9–10).

ANALYSIS

A. Sufficiency of Factual Allegations

Before the Court may address Allergan's preemption arguments, it first must consider Allergan's argument that Ms. Rice has failed to allege sufficient facts to support her claims. *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1328 (11th Cir. 2017) (quoting *Slack v. McDaniel*, 529 U.S. 473, 485 (2000) for the proposition that "courts should 'not pass upon a constitutional question although properly presented by the record, if there is also present some other ground upon which the case may be disposed of.'"). Under Rule 12(b)(6), a district court must determine whether a complaint contains "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "Determining whether a complaint states a plausible claim for relief will [ultimately] . . . be a context-specific task that requires [a district court] to draw on its judicial experience and

common sense." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

Ms. Rice "concedes a lack of factual support at this time to plead parallel [state] claims" as to her third, fourth, fifth, and seventh causes of action and "concedes to dismissal of those specific claims without prejudice." (Doc. 26, p. 1). Accordingly, the Court dismisses Ms. Rice's claims for design defect, manufacturing defect, breach of warranty, and violation of ADTPA without prejudice. This leaves Ms. Rice's claims for negligence, failure to warn, and negligent or fraudulent misrepresentation. (Doc. 18).

1. Negligence

Under Alabama law, to establish a claim for negligence, "the plaintiff must prove: (1) a duty to a foreseeable plaintiff; (2) a breach of that duty; (3) proximate causation; and (4) damage or injury." *Lemley v. Wilson*, 178 So. 3d 834, 841–42 (Ala. 2015), *reh'g denied* (Apr. 17, 2015) (quoting *Martin v. Arnold*, 643 So. 2d 564, 567 (Ala. 1994)). In support of her negligence claim, Ms. Rice alleges, among other things, that Allergan "breached federal device requirements and parallel Alabama law duties to exercise reasonable and prudent care in development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, sale, post-market surveillance and adverse events reporting of the LAP-BAND" by (1) manufacturing a device that presented "an unreasonable risk of failure, particularly over time, as it relates to band erosion and perforation,"

(2) designing and manufacturing a device "with insufficient strength or structural integrity to withstand long term placement within the human body, a manner for which the device was indicated," (3) "marketing and recommending to Plaintiff and her physician the use of the LAP-BAND in such a manner as to misrepresent the safety and efficacy of the device, including the heightened risk of device-associated complications over time"; (4) "failing to provide adequate labeling for the LAP-BAND device when it knew or should have known the safety and efficacy of the device was being misrepresented in its labeling"; (5) "failing to place into effect 'labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction,' or that 'add or strengthen an instruction that is intended to enhance the safe use of the device,' or 'that delete misleading, false or unsupported indications'"; (6) "failing to report required adverse events associated with the LAP-BAND to the FDA, thereby preventing the dissemination of key safety information to Plaintiff and her physician prior to and after Plaintiff was implanted the device"; and (7) "failing to perform post-market surveillance regarding the long-term safety and efficacy of the LAP-BAND." (Doc. 18, ¶ 49). Ms. Rice alleges that these breaches of Allergan's duties to her caused her to suffer gastric perforation when her LAP-BAND failed over time. (Doc. 18, ¶¶ 40, 50). These allegations describe a plausible claim for negligence against Allergan with regard to its designing, manufacturing,

marketing, labeling, reporting, and surveillance of the LAP-BAND.

2. Strict Liability - Failure to Warn

Under Alabama law, to establish a claim for failure to warn, the plaintiff must prove: (1) the defendant supplies a product for another to use; (2) the defendant "knows or has reason to know that the [product] is or is likely to be dangerous for the use for which it is supplied"; (3) the product's dangerous condition is not obvious to the user; (4) the defendant "fails to exercise reasonable care to inform [the user] of [the product's] dangerous condition or of the facts which make it likely to be dangerous"; and (5) the product causes physical harm "in the manner for which and by a person for whose use it is supplied." *Ex parte Chevron Chem. Co.*, 720 So. 2d 922, 924–25 (Ala. 1998) (quoting Restatement (Second) of Torts § 388 (Am. Law. Inst. 1975)). Ms. Rice alleges that Allergan supplied the LAP-BAND, Allergan knew or should have known of studies showing that the LAP-BAND was dangerous, particularly with respect to the risk of failure over time, this risk was not obvious to Ms. Rice or her physician, Allergan did not update its warnings, and Ms. Rice suffered a perforated stomach because of the LAP-BAND's failure over time. (Doc. 18, ¶¶ 26–37, 50, 55, 60, 63). These allegations, taken as true, describe a plausible claim against Allergan for failing to warn Ms. Rice of the dangerous condition of the LAP-BAND.

3. Fraudulent Misrepresentation

Under Alabama law, to establish a claim for fraudulent misrepresentation, the plaintiff must prove: (1) the defendant made a false representation; (2) the misrepresentation involved a material fact; (3) the plaintiff relied on the misrepresentation; and (4) the misrepresentation damaged the plaintiff. *Target Media Partners Operating Co., LLC v. Specialty Mktg. Corp.*, 177 So. 3d 843, 863 (Ala. 2013) (quoting *AmerUs Life Ins. Co. v. Smith*, 5 So. 3d 1200, 1207 (Ala. 2008)).

Ms. Rice alleges that Allergan represented "to the public, the medical community and Plaintiff's health care providers" in "reports, press releases, advertising campaigns, labeling materials, print advertisements, [and] commercial media" that the LAP-BAND was fit for human use when, in fact, "[t]he LAP-BAND is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner" because the LAP-BAND "has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered" and because the LAP-BAND "has a significantly higher rate of failure and injury than do other comparable devices." (Doc. 18, ¶ 94). Ms. Rice also alleges that she relied upon Allergan's false representations that the LAP-BAND was safe when she decided to have the LAP-BAND implanted and that the LAP-BAND caused her to suffer a gastric perforation. (Doc. 18, ¶ 95). Ms. Rice plausibly asserts that Allergan is liable for fraudulent misrepresentation. (*See* Doc.

18, ¶¶ 31, 32, 58).

Accordingly, Ms. Rice has alleged adequate facts to assert Alabama state law claims for negligence, strict liability failure to warn, and fraudulent misrepresentation against Allergan.

B. Preemption

"[P]reemption is a principal derived from the Supremacy Clause" of the United States Constitution. *Mink*, 860 F.3d at 1328 (citing U.S. Const. Art. VI, cl. 2). When preemption applies, a "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). "A federal statute may preempt state law either expressly, by the statute's language, or implicitly, by the statute's structure and purpose." *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1371 (11th Cir. 1999) (citing *Cipollone*, 505 U.S. at 516). "In the absence of an express command, federal law will preempt state law if that law actually conflicts with federal law or if the federal law 'so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.'" *Goodlin.*, 167 F.3d at 1371 (quoting *Cipollone*, 505 U.S. at 516).

Allergan argues that the Medical Device Amendments of 1976, 21 U.S.C. § 360c et seq., preempt Ms. Rice's state law claims. (Doc. 24, pp. 15–31). "The Medical Device Amendments gave the FDA regulatory authority over medical

devices for human use." *Mink*, 860 F.3d at 1325 (citing 21 U.S.C. § 360c et seq.). "Under that authority, the FDA classifies medical devices into three categories, depending on the level of risk presented." *Mink*, 860 F.3d at 1325 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17 (2008)). The LAP-BAND, as a "device intended for human use," is a class III medical device. *See* 21 U.S.C. § 360c(f)(1). Accordingly, the LAP-BAND is subject "to premarket approval to provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C).

> Premarket approval is a rigorous process of federal review that evaluates a medical device's safety and effectiveness. This process takes, on average, about 1,200 hours of review by the FDA. For each device, the FDA compiles a large amount of data and carefully weighs the risks and benefits. Even once approved, the FDA regularly attaches specific conditions to a device. And after the FDA approves a device, the manufacturer may not make any change to the device's specifications, or anything else that might affect its safety and effectiveness, unless it submits a supplemental application to the FDA. The FDA must be informed of changes to the manufacturing process. The manufacturer must report information to the FDA, including new studies about the device and any adverse events.

Mink, 860 F.3d at 1325 (internal citations omitted).

The Medical Device Amendments contain both express and implied preemption provisions. *Mink*, 860 F.3d at 1325 (citing 21 U.S.C. § 360k(a); 21 U.S.C. § 337(a)). The express preemption provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement

> applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). "This provision does not allow a state to impose a requirement on a Class III medical device that is 'different from, or in addition to' any federal requirement on the device." *Mink*, 860 F.3d at 1325 (quoting 21 U.S.C. § 360k(a)). Accordingly, "[a]ny state requirement that does this is expressly preempted by federal law." *Mink*, 860 F.3d at 1325. But "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Mink*, 860 F.3d at 1326 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

This "parallel claim principle" requires a plaintiff to show that the state and federal requirements are "genuinely equivalent." *Mink*, 860 F.3d at 1326 (quoting *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011)). "[A] claim that a device 'violated state tort law notwithstanding compliance with the relevant federal requirements' would clearly be preempted." *Mink*, 860 F.3d at 1326 (quoting *Riegel*, 552 U.S. at 330). A plaintiff must allege "what parallel federal requirements" have been violated. *Mink*, 860 F.3d at 1326; *see also Wolicki-Gables*, 634 F.3d at 1301 ("'To properly allege parallel claims, the

complaint must set forth facts' pointing to specific PMA requirements that have been violated.") (quoting *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008)).

The implied preemption provision in the MDA "requires that, with exceptions not relevant here, 'all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Mink*, 860 F.3d at 1327 (emphasis omitted) (quoting 21 U.S.C. § 337(a)). "This is sometimes called the 'no-private-right-of-action' clause.'" *Mink*, 860 F.3d at 1327. Under this provision, the MDA impliedly preempts a plaintiff's state-law claim when a plaintiff "assert[s] the power given to the FDA to punish and deter fraud against itself." *Mink*, 860 F.3d at 1327 (citing *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001)). "[T]raditional state-law tort claims survive implied preemption so long as" a plaintiff does not "seek to privately enforce a duty owed to the FDA." *Mink*, 860 F.3d at 1327 (citing *Buckman*, 531 U.S. at 348). Taken together, express and implied preemption

> leave a "narrow gap" through which plaintiffs making medical device claims must proceed. *See In re Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010). "To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." *Mink*, 860 F.3d at 1327. Put differently, "a plaintiff may proceed on her claim so long as she claims the 'breach of a well-recognized duty owed to her under state law' and so 'long as she can show that she was harmed by a violation of applicable federal law.'" *Id.* (quoting *Bausch v. Stryker*

Corp., 630 F.3d 546, 558 (7th Cir. 2010)).

Godelia v. Doe 1, 881 F.3d 1309, 1317 (11th Cir. 2018).

1. Negligence

Ms. Rice asserts that Allergan is liable for negligent design and manufacture of the LAP-BAND in that the product, among other things, presented "an unreasonable risk of failure, particularly over time, as it relates to band erosion and perforation" and had "insufficient strength or structural integrity to withstand long term placement within the human body, a manner for which the device was indicated." (Doc. 18, ¶ 47(b)). Ms. Rice also alleges that the LAP-BAND was "designed and manufactured in such a manner as to present an unreasonable risk of associated harm to other organ systems in the body." (Doc. 18, ¶ 47(c)). Ms. Rice states that "[a]t the time of manufacture and sale of the LAP-BAND, Defendant knew or should have known that using the LAP-BAND in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to, band erosion and perforation necessitating reoperation and/or device removal and organ system repair." (Doc. 18, ¶ 48). Ms. Rice has not alleged that Allergan's duty under Alabama law to use reasonable care when manufacturing a product parallels the federal requirement that the LAP-BAND be "manufactured according to the approved specifications for the medical device" pursuant to 21 C.F.R. § 814.80.

Compare Mink, 860 F.3d at 1330; *see also id.* at 1331.

Ms. Rice offers additional theories of negligent manufacture which she tethers to federal regulations. Those theories are negligent marketing, negligent labeling, negligent failure to update labeling, negligent reporting, and negligent surveillance. She bases those negligence theories on alleged violations of 21 C.F.R. §§ 99.101, 801.4, 814.39, 803.50, and 822.25, respectively.

The MDA does not impliedly preempt Ms. Rice's state law claims for negligent design and manufacture of the LAP-BAND based on her contention that the device presented an unreasonable risk of failure, particularly over time; lacked sufficient strength or structural integrity to withstand long term placement within the human body; and presented an unreasonable risk of associated harm to other organ systems. These "traditional state law causes of action [] predated the federal enactments," and they do not "implicate a duty owed to the FDA." *Mink*, 860 F.3d at 1330; *Godelia v. Doe 1*, 881 F.3d 1309, 1318 (11th Cir. 2018); *Gulledge v. Brown & Root, Inc.*, 598 So. 2d 1325 (Ala. 1992). Rather, the duty runs to Ms. Rice. As currently pleaded, the MDA expressly preempts these state law negligent design and manufacturing theories because Ms. Rice has not alleged "what parallel federal requirements" have been violated, an omission that Ms. Rice potentially may remedy by amendment. *Mink*, 860 F.3d at 1326.

The MDA preempts Ms. Rice's other negligent manufacturing theories. Ms.

Rice alleges that Allergan violated 21 C.F.R. § 99.101 by "marketing and recommending to Plaintiff and her physician the use of the LAP-BAND in such a manner as to misrepresent the safety and efficacy of the device." (Doc. 18, ¶ 49(a)). Pursuant to § 99.101, "[a] manufacturer may disseminate written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling . . . provided that the manufacturer complies with all other relevant requirements under this part." 21 C.F.R. § 99.101(a). This section imposes no affirmative obligation on manufacturers. Instead, it sets guidelines for the dissemination of additional information if a manufacturer wishes to provide such information. Ms. Rice has not alleged that Allergan chose to disseminate additional information but failed to follow the guidelines in this section; she alleges that Allergan did not choose to provide additional information about LAP-BAND erosion rates. This allegation does not state a violation of 21 C.F.R. § 99.101. Because Ms. Rice does not allege facts to show that Allergan violated this federal regulation, federal law expressly preempts her claim for negligent marketing. *See Mink*, 860 F.3d at 1326.

Ms. Rice alleges that Allergan violated 21 C.F.R. § 801.4 by "failing to provide adequate labeling." (Doc. 18, ¶ 49(b)). This regulation defines the term "intended uses" as it appears in various regulations regarding the labeling of medical devices. 21 C.F.R. § 801.4 (referencing 21 C.F.R. §§ 801.5, 801.119,

801.122). Ms. Rice does not allege that Allergan violated this definition. Thus, because Ms. Rice does not allege facts to show that Allergan violated this federal requirement, federal law expressly preempts this negligent labeling theory. *See Mink*, 860 F.3d at 1326.

Ms. Rice alleges that Allergan violated 21 C.F.R. § 814.39 by "failing to place into effect 'labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction,' or that 'add or strengthen an instruction that is intended to enhance the safe use of the device,' or 'that delete misleading, false or unsupported indications.'" (Doc. 18, ¶ 49(c)). This regulation allows manufacturers to make labeling changes "that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association," or "that add or strengthen an instruction that is intended to enhance the safe use of the device," or "that delete misleading, false, or unsupported indications" while a manufacturer awaits "a written FDA order approving the PMA supplement." 21 C.F.R. § 814.39(d). Because Ms. Rice has not alleged that Allergan was awaiting an FDA order approving a supplement to its labelling, the Court cannot determine whether this regulation applied to Allergan. Therefore, as pleaded, federal law expressly preempts her claim for negligent failure to update labeling. *See Mink*, 860 F.3d at 1326.

Ms. Rice alleges that Allergan violated 21 C.F.R. 803.50 by "failing to report required adverse events." (Doc. 18, ¶ 49(d)). This section requires manufacturers to report to the FDA "information, from any source, that reasonably suggests that" a device "[m]ay have caused or contributed to a death or serious injury" or "[h]as malfunctioned and . . . would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a). Ms. Rice alleges that studies showed a higher rate of erosion than Allergan disclosed in its labeling, and Allergan did not report the "adverse events associated with the LAP-BAND to the FDA, thereby preventing the dissemination of key safety information to [her] and her physician" before her physician implanted the device. (Doc. 18, ¶ 49(d)). Erosion could be considered a "serious injury" under § 803.50(a).

Because Ms. Rice alleges facts which show that Allergan violated a federal reporting requirement, the MDA does not expressly preempt her claim. Alabama law recognizes "the common law duty of failure to warn as a basis for a negligence claim" in a products liability action, a theory that embraces her failure to report theory. *Mink*, 860 F.3d at 1329; *see Chevron Chem.*, 720 So. 2d at 924–25 (quoting Restatement (Second) of Torts § 388). Still, the MDA impliedly preempts Ms. Rice's failure to report claim because her claim rests on her allegation that Allergan "failed to tell the FDA those things required by federal

law." *See Mink*, 860 F.3d at 1330.

Ms. Rice alleges that Allergan violated 21 C.F.R. § 822.25 by "failing to perform post-market surveillance." (Doc. 18, ¶ 49(e)). This regulation requires manufacturers to "conduct the postmarket surveillance" in accordance with an FDA-approved plan. 21 C.F.R. § 822.25. Assuming that Ms. Rice has sufficiently alleged that Allergan violated its duty under this federal regulation, Ms. Rice has not identified a traditional state law cause of action for post-market surveillance that predated the MDA. She simply states that Allergan's alleged failure to "perform post-market surveillance" violated Alabama law. Thus, the MDA impliedly preempts this theory as pleaded.

2. Strict Liability - Failure to Warn

Ms. Rice bases her strict liability failure to warn claim on the theories she asserts as the basis for her negligence claim. Therefore, the analysis of her negligence theories applies equally to her strict liability theories.

3. Misrepresentation

Ms. Rice pleads a claim for negligent or fraudulent misrepresentation under Alabama law based on Allergan's false assurances of the "quality of the LAP-BAND and its fitness for use" and based on Allergan's failure to disclose the fact that its product is not "safe, fit, and effective for human use in its intended and reasonably foreseeable manner." (Doc. 18, ¶¶ 91-100). Ms. Rice contends that

Allergan published quality assurances in, among other things, press releases, "labeling materials" and "print advertisements" that Allergan distributed to her, to her health care providers, and to the medical community in general. (Doc. 18, ¶¶ 91–92). Ms. Rice alleges that in reliance on Allergan's "false and negligent misrepresentations and omissions," she and her "health care providers were induced to, and did use the LAP-BAND," causing her "to sustain severe and permanent injuries." (Doc. 18, ¶ 95).

The Court cannot tell from these general allegations whether Ms. Rice contends that in its press releases and advertisements, Allergan "held its product out as meeting a higher standard than that required by the FDA." *Godelia*, 881 F.3d at 1322. If so, then Ms. Rice may pursue her claims for negligent or fraudulent misrepresentation because Alabama law recognizes these claims. *See Godelia*, 881 F.3d at 1320–22; *Target Media Partners*, 177 So. 3d at 863. To the extent that Ms. Rice alleges that Allergan suppressed information that the company should have disclosed, if those disclosure requirements demand more than the FDA required Allergan to disclose, then the MDA preempts Ms. Rice's suppression theory, even though Alabama tort law recognizes claims for fraudulent suppression, because Alabama law would impose a duty greater than the federal duty under the MDA. *See Mink*, 860 F.3d at 1326.

CONCLUSION

As currently pleaded, Ms. Rice has not adequately stated a claim against Allergan. Accordingly, the Court **GRANTS** Allergan's motion to dismiss Ms. Rice's negligence, strict liability failure to warn, and negligent misrepresentation claims as currently pleaded and allows Ms. Rice to voluntarily dismiss the balance of her claims without prejudice. If Ms. Rice wishes to replead some or all of her claims, she must file an amended complaint **on or before April 16, 2018**. If Ms. Rice does not file an amended complaint on or before April 16, 2018, the Court will enter an order instructing the Clerk to please close the file.

DONE and **ORDERED** this April 4, 2018.

Madeline H. Haikala

MADELINE HUGHES HAIKALA
UNITED STATES DISTRICT JUDGE